

Art Unit: 1641

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Julia Dierker on May 28, 2010.

Please amend the claims as follows:

1. A self-calibrating, disposable blood test device insertable in a meter, the test device comprising:

a substrate configured for carrying a chemical reagent; and
circuitry formed on the substrate, the circuitry comprising:

a sensor portion associated with the chemical reagent to enable measurement of at least one of a presence and a concentration of a blood analyte, the sensor portion including an electrode sensor;

an input/output pad connected to the electrode sensor; and

an additional input/output pad connected to an information storage portion that is connected in parallel with the electrode sensor;

[[an]] wherein the information storage portion is configured to store information indicative of a property of the chemical reagent at least one calibration value of the chemical reagent for calibrating operation calibration of the meter, the information storage portion including a plurality of impedance elements including at least one of: a plurality of inductors arranged in series; or a plurality of capacitors arranged in parallel, wherein each impedance element includes a region that may be physically altered by at least one of punching, drilling, or shorting via fusible link, to create a short circuit or

Art Unit: 1641

~~open circuit, in order to activate or deactivate the impedance element to accurately measure and monitor a test of the blood analyte, the at least one calibration value being indicative of a property of the chemical reagent; and~~

~~an input and output arrangement formed on the substrate and in electrical communication with the information storage portion to enable the meter to access the at least one calibration value from the information storage portion;~~

~~wherein no other source of calibration information separate from the information storage portion on the disposable blood test device is required for calibration of the meter;~~

~~wherein the information storage portion is stored by activating or deactivating a select number of electrically connected to a portion of the sensor portion of the circuitry and includes at least one electrically conductive element including a plurality of impedance elements, each impedance element being configured to be physically altered by at least one of punching, drilling, and shorting via fusible link and a number, N, of the impedance elements in a determinable order, which creates a producing characteristic impedance between the input/output pad and the additional input/output pad that is measurable by the meter and which corresponds to at least one calibration value that is indicative of the property at least one calibration value of the chemical reagent[.,.];~~

~~and wherein the [[N]] impedance elements within the information storage portion are arranged such that producing 2^N different potential characteristic impedances may be produced, wherein N is the number of impedance elements possible calibration values; and~~

~~wherein the plurality of impedance elements includes at least one of: a plurality of inductors arranged in series or a plurality of capacitors arranged generally in parallel; the plurality of inductors, the plurality of capacitors or a combination thereof all being arranged between a portion of the sensor portion and an input and output conductive element of the information storage portion.~~

2 - 6. (Cancelled)

7. The test device of claim 1, wherein the test device comprises one of a set of test devices with the information storage portion of each test device storing substantially the same

Art Unit: 1641

information in the information storage portion to be indicative of the at least one calibration value of the chemical reagent for the set of test devices.

8. The test device of claim 1, wherein the circuitry of the substrate comprises a semiconductor portion and the circuitry defines a non-volatile memory configured to store the information.

9. The test device of claim 8, ~~[[and]]~~ further comprising an electrical signal generator external to the test device and configured to send an electrical signal to the non-volatile memory to cause storage of the information in the information storage portion of the test device.

10. The test device of claim 8, wherein the non-volatile memory is configured to also store at least one of a date of manufacture, an operating characteristic, and serial number.

11. A method of manufacturing a test device insertable in a meter for the detection of a blood analyte, the method comprising:

forming circuitry on a substrate of the test device, the substrate configured for carrying a chemical reagent, and the circuitry including:

a sensor portion associated with the chemical reagent to enable measurement of at least one of a presence and a concentration of a blood analyte, the sensor portion including an electrode sensor;

an input/output pad connected to the electrode sensor; and

an additional input/output pad connected to an information storage portion that is connected in parallel with the electrode sensor;

~~[[an]]~~ wherein the information storage portion is configured to store information indicative of a property of the chemical reagent at least one calibration value of the chemical reagent for calibrating operation calibration of the meter, the information storage portion including a plurality of impedance elements including at least one of: a plurality of inductors arranged in series; or a plurality of capacitors arranged in parallel, wherein each impedance element includes a region that may be physically altered by at

Art Unit: 1641

least one of punching, drilling, or shorting via fusible link, to create a short circuit or open circuit, in order to activate or deactivate the impedance element to accurately measure and monitor a test of the blood analyte, the at least one calibration value being indicative of a property of the chemical reagent; and

an input and output arrangement formed on the substrate and in electrical communication with the information storage portion to enable the meter to access the at least one calibration value from the information storage portion;

depositing the chemical reagent on the sensor portion that enables detection of the blood analyte; and

storing information in the information storage portion ~~that is indicative of the at least one calibration value of the test device;~~

~~wherein no other source of calibration information separate from the information storage portion on the disposable blood test device is required for calibration of the meter;~~

wherein the information ~~storage portion~~ is stored by activating or deactivating a select number of electrically connected to a portion of the sensor portion of the circuitry and includes at least one electrically conductive element including a plurality of impedance elements, each impedance element being configured to be physically altered by at least one of punching, drilling, and shorting via fusible link and a number, N, of the impedance elements in a determinable order, which creates a producing characteristic impedance between the input/output pad and the additional input/output pad that is measurable by the meter and which corresponds to at least one calibration value that is indicative of the property at least one calibration value of the chemical reagent[[,]];

and wherein the [[N]] impedance elements within the information storage portion are arranged such that producing 2^N different potential characteristic impedances may be produced, wherein N is the number of impedance elements possible calibration values; and

and wherein the plurality of impedance elements includes at least one of: a plurality of inductors arranged in series or a plurality of capacitors arranged generally in parallel; the plurality of inductors, the plurality of capacitors or a combination thereof all being arranged between a portion of the sensor portion and an input and output conductive element of the information storage portion.

12. The method of claim 11, further comprising:

determining a property of the test device, the property of the test device being selected from the at least one calibration value of the chemical reagent, a date of manufacture, an analyte array identifier, and an operating characteristic.

13. The method of claim 12, wherein storing information in the information storage portion comprises storing at least one of the at least one calibration value of the chemical reagent, the date of manufacture, the analyte array identifier, and the operating characteristic.

14. The method of claim 11, wherein forming the information storage portion of the circuitry comprises forming a thin film circuitry portion on the substrate that defines a non-volatile memory portion, and wherein storing information in the information storage portion comprises sending an electrical signal to the information storage portion to store a value in the non-volatile memory portion.

15. (Cancelled)

16. The method of claim 11, further comprising:

measuring the at least one calibration value of the chemical reagent to determine a calibration factor for the test device[[,]];

[[and]] wherein storing information in the information storage portion comprises altering at least one of the plurality of impedance elements, wherein the number of altered impedance elements is indicative of the calibration factor of the test device.

17. The method of claim 16, wherein altering the plurality of impedance elements comprises disabling at least one of the plurality of impedance elements by at least one of physically removing a conductive portion of the impedance element and physically adding a conductive portion to the impedance element.

Art Unit: 1641

18 - 19. (Cancelled)

20. The test strip of claim [[18]] 1, wherein the information storage portion ~~means for electrically storing~~ is inseparable from the disposable test strip.

21. (Cancelled)

Please add the following claim 22:

22. The test device of claim 1 wherein:

the electrode sensor includes first and second electrode sensors;

the input/output pad includes:

a first input/output pad connected to the first electrode sensor; and

a second input/output pad connected to the second electrode sensor; and

the characteristic impedance is created between the second input/output pad and the additional input/output pad.

Please cancel claims 18 and 21.

2. Claims 1, 7-10, 20, 21 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 11-14, 16, 17, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on November 27, 2007 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a

Art Unit: 1641

continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Please renumber 1, 7-14, 16, 17, 20, 22 as claims 1-13 respectively.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/

Primary Examiner, Art Unit 1641